

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----- X
IN RE PROPECIA (FINASTERIDE)
PRODUCT LIABILITY LITIGATION

THIS DOCUMENT APPLIES TO:

PAUL DAWSON,

Plaintiff,

v.

MERCK & CO., INC. and MERCK SHARP &
DOHME CORP.,

Defendants.
----- X

Master File No.: 12-md-2331 (BMC)(PK)

Case No.: 1:12-cv-01876 (BMC)(PK)

ORAL ARGUMENT REQUESTED

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF
PROPOSED INTERVENOR REUTERS' MOTION TO INTERVENE AND UNSEAL
IN RESPONSE TO THE OPPOSITIONS FILED BY PLAINTIFF AND DEFENDANTS**

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PRELIMINARY STATEMENT

In their oppositions to Reuters’ Motion to Intervene and Unseal, both Plaintiff and Defendants fail to proffer any compelling reasons why the Sealed Exhibits should remain fully obstructed from public access or why the Redacted Brief should remain redacted.

As an initial matter, neither party appears to contest that it is proper for Reuters to intervene in this action, and its motion to intervene should accordingly be granted. Instead, the parties address only Reuters’ claim to unseal documents, but none of their arguments is persuasive.

First, Plaintiff argues that Reuters should not receive access to his protected medical records—a point that Reuters does not dispute. Second, Defendants use their brief more as an opportunity to criticize Reuters’ well-researched articles than as an opposition to Reuters’ motion to unseal. At its crux, Defendants’ opposition argues that because *Merck* believes it has been forthcoming with some of the information under seal, there is no reason for the Court to release any of the Sealed Exhibits to the public. But a party’s subjective belief of its own transparency plays no role in a constitutional access analysis. Neither should Defendants’ generalized allegations that they may suffer competitive harm if these decades-old documents are released to the public. In fact, Defendants’ opposition emphasizes why unsealing is necessary. Neither a Reuters journalist nor any other citizen is required to take Merck’s characterization of its “transparent” behavior before the FDA and this Court at face value. The First Amendment provides the public with a right of access to these proceedings so they can judge for themselves.

Accordingly, because the Sealed Exhibits are judicial documents subject to a strong presumption of access and because the Court has never made specified findings about the propriety of sealing them, the Court should allow Reuters to intervene in this case, should vacate the prior sealing order, and should mandate that the parties un-redact the Redacted Brief and produce the Sealed Exhibits (redacting any highly sensitive personal or privileged information).

ARGUMENT

A. Reuters' Motion to Intervene Should Be Granted

“[C]ourts have repeatedly recognized that members of the press (and other non-parties) may seek to pursue modification of confidentiality orders that have led to the sealing of documents filed with the court, and that the appropriate procedural mechanism to do so is a motion to intervene.” *In re Pineapple Antitrust Litig.*, 2015 WL 5439090, at *1 (S.D.N.Y. Aug. 10, 2015). Because neither party seems to oppose Reuters' motion to intervene, the Court should grant it.¹

B. The Court's Sealing Order Should Be Vacated

In its Opening Brief (ECF No. 121), Reuters argued that the Court's order sealing all documents in the first instance was improper. *See* Mot. 10-11. Neither party appears to meaningfully dispute this argument—Plaintiff does not address it at all, and Defendants do so only briefly, arguing that “Reuters does not cite to or present any specific action to demonstrate that the Court did not review documents in conjunction with the appropriate sealing mechanisms ordered by this Court.” Defs. Opp'n 14. Putting aside that Defendants expect Reuters to prove the impossible (that the Court did not secretly review the Sealed Exhibits and decide to itself that sealing was proper without making on-the-record findings), Defendants' argument still misses the point—Reuters takes issue not merely with the Court's failure to follow its own sealing order but with the sealing order itself. As courts in the Second Circuit have recently affirmed, “[a] protective order authorizing the parties themselves to designate confidential material and to file such material under seal – without prior ‘individualized review’ and ‘specific, on-the-record findings’ by the

¹ Defendants argue that Reuters failed to comply with Rule III.A.2 of the Court's Individual Practices because it did not request a pre-motion conference. *See* Defs. Opp'n 1 n.1. However, that Rule states, “**Parties** must request a pre-motion conference in writing by ECF.” However, Reuters – as a proposed intervenor – is not a party to this dispute, and that Rule is therefore inapplicable. *See Abdelal v. Kelly*, 2017 WL 1843291, at *1 (S.D.N.Y. May 5, 2017) (“A third party, such as the New Yorker, is entitled to request that the Court modify a protective order. It may not, however, do so merely by filing an informal request with the Court; rather, it **must** file a formal notice of motion to intervene in the case under Federal Rule of Civil Procedure 24.”) (emphasis added).

Court that such sealing or redactions is warranted – is inappropriate.” *New York ex rel. Khurana v. Spherion Corp.*, 2019 WL 3294170, at *2 (S.D.N.Y. July 19, 2019). Because the sealing order in this case permitted the parties to seal documents prior to the Court determining, on the record, whether such sealing was appropriate, it violated the First Amendment and common law rights of access. For this reason alone, Reuters’ motion to unseal should be granted.

C. Plaintiff’s Arguments

Plaintiff’s only substantive argument is that some of the Sealed Exhibits contain Plaintiff’s confidential health information, which is protected under the Health Insurance Portability and Accountability Act (“HIPPA”). *See* Pl. Opp’n ¶¶ 6-9. But as Reuters stated in its Opening Brief, it is not seeking to publicly reveal personal or privileged information. *See* Mot. 14. (“To the extent the Sealed Documents do contain any personal or privileged information . . . they can still be provided to the public with narrow redactions.”). If any of the Sealed Exhibits contain Plaintiff’s HIPPA-protected medical information, Reuters would neither request nor expect this Court to unseal such documents in full. At the same time, the fact that some documents may contain personal information is not a reason to keep all twenty-eight Exhibits completely sealed.

D. Defendants’ Arguments

1. The Sealed Exhibits Are Judicial Documents

Recognizing that “judicial documents” are subject to a presumptive right of access, Defendants allege that the Sealed Exhibits are not judicial documents and there is no presumption of access to them. *See* Defs. Opp’n 8-10. But the Second Circuit has held time and time again that documents attached to motions filed with the court – including *Daubert* motions, as in this case – are judicial documents to which the presumption of access applies. *See Brown v. Maxwell*, 929 F.3d 41, 50 (2d Cir. 2019) (documents submitted with discovery and evidentiary motions are judicial documents); *Louis Vuitton Malletier S.A. v. Sunny Merch. Corp.*, 97 F. Supp. 3d 485, 511-

12 (S.D.N.Y. 2015) (materials filed in connection with motion to disqualify expert deemed judicial documents); *Wells Fargo Bank, N.A. v. Wales LLC*, 993 F. Supp. 2d 409, 412 (S.D.N.Y. 2014) (“Generally, documents filed in relation to a motion are judicial documents to which a presumption of immediate public access attaches under both the common law and the First Amendment.”).

In addition, the Sealed Exhibits were not merely related to Plaintiff’s opposition to Defendants’ *Daubert* motion but, as discussed further below, were also incorporated into Plaintiff’s opposition to summary judgment. It is “well-settled that documents submitted to a court for its consideration in a summary judgment motion are—as a matter of law—judicial documents.” *Brown*, 929 F.3d at 47; *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 121 (2d Cir. 2006) (“[T]here is a presumption of access to documents submitted on a summary judgment motion.”). Accordingly, the Sealed Exhibits are judicial documents.

Defendants attempt to distract the Court from this simple point by re-litigating the underlying *Daubert* motion, which the Court did not decide prior to the case’s settlement. According to Defendants, because Plaintiff’s argument in opposition to their *Daubert* motion – namely that Plaintiff’s experts’ methodologies were reliable because they reached the same conclusions as Merck – was weak, the Court would not have needed to rely upon the Sealed Exhibits when deciding Defendants’ motion. *See* Defs. Opp’n 9-10. As a result, Defendants allege, the Sealed Exhibits are not “judicial documents.” But even if Defendants’ crystal ball is clear and the Court had not used the Sealed Exhibits when determining whether to disqualify Plaintiff’s experts (or whether to grant Defendants’ corresponding motion for summary judgment), this does not alter their status as judicial documents. To the contrary, the Second Circuit has held that documents do not lose their status as “judicial documents” merely because the documents do not influence the Court’s decision. *See Brown*, 929 F.3d at 49; *United States v. Sattar*, 471 F.

Supp. 2d 380, 385 (S.D.N.Y. 2006) (even though “[t]he Court did not find the submissions to be useful and did not rely on them,” because they were “submitted to the Court for purposes of seeking or opposing an adjudication,” the documents were judicial documents). That Merck found Plaintiff’s arguments unpersuasive does not make the documents unprivileged.

Defendants also argue the Sealed Exhibits are not judicial documents because they are cited in the “first nine pages” (the “facts” section) of Plaintiff’s opposition brief. Defs. Opp’n 9. As an initial matter, Defendants point to no case law that suggests that legal arguments are privileged but factual statements are not. Just the opposite is true—there is a presumption that “parties may ‘be assumed to have supported their papers with admissible evidence and non-frivolous arguments.’” *Brown*, 929 F.3d at 47 n.12 (citation omitted). In addition, as a factual matter and contrary to Defendants’ assertions, the Sealed Exhibits are not merely mentioned in the first nine pages but are instead discussed throughout Plaintiff’s brief, including on page 11 in a summary of the contested experts’ background information and in the argument section on pages 24, 29, and 41. And the “facts” section, which included the results of Merck’s internal studies on the relationship between Propecia and erectile dysfunction, informed Plaintiff’s arguments that its expert opinions were accurate and that it could prove causation. Accordingly, even under Defendants’ incorrect conception of “judicial documents,” the Sealed Exhibits qualify as such.

2. *There Is a Strong Presumption of Access to the Sealed Exhibits*

Defendants argue that, even if the Sealed Exhibits are “judicial documents,” the presumption of access is “exceedingly weak” because the documents are attached to an opposition to a *Daubert* motion (which Defendants call a “non-dispositive discovery motion”). See Defs. Opp’n 7, 10-12. But as Reuters previously explained, the documents are still entitled to the “highest” First Amendment presumption of access because they closely relate to Plaintiff’s opposition to summary judgment. See Mot. 9-10; *Brown*, 929 F.3d at 47 (noting that a “strong

presumption of access attaches, under both the common law and the First Amendment” to “documents submitted to a court for its consideration in a summary judgment motion”).

Hoping to avoid *Brown*, Defendants argue in favor of form over substance, claiming it “would be easy to articulate some relationship between nearly any evidentiary motion and a motion for summary judgment.” But Defendants’ *Daubert* motion is not just “any” evidentiary motion—Defendants filed it the same day as their summary judgment motion and stated, “Merck adopts and incorporates by reference its Motion to Exclude Plaintiff’s Experts, filed contemporaneously with this Motion.” ECF No. 110 at 1 n.1. Plaintiff similarly stated that he “incorporated” his opposition to the *Daubert* motion into his summary judgment opposition. ECF No. 114 at 5.²

Defendants offer only two other arguments for why the Sealed Exhibits are entitled to an “exceedingly weak” presumption of access, neither of which is persuasive:

First, Defendants claim that no plaintiff in any of the Propecia lawsuits has requested that the Court unseal documents. *See* Defs. Opp’n 12. But courts have recognized that the interests represented by media organizations as proxies for the public differ from a plaintiff’s. *See Schiller v. City of N.Y.*, 2006 WL 2788256, at *3 (S.D.N.Y. Sept. 27, 2006) (“[T]here is no reason to believe that the Times’ concerns are coextensive with those of the plaintiffs such that the Times’ interests would be adequately represented by plaintiffs’ counsel.”); *Diversified Grp., Inc. v. Daugerdas*, 217 F.R.D. 152, 158 (S.D.N.Y. 2003) (“Moreover, ALM has demonstrated a legitimate interest in disclosure of the documents at issue—*i.e.*, to provide readers with a complete story regarding the development and use of particular tax strategies—and ALM’s interest is not represented by the other parties, all of whom seek to maintain the confidentiality of the record.”). Accordingly, even when the parties to a case enter into a confidentiality agreement, courts allow third parties, like

² Further, as courts in this Circuit have recognized, documents filed in connection with *Daubert* motions are, on their own, subject to the First Amendment presumption of access. *See Louis Vuitton*, 97 F. Supp. at 510, 512.

media organizations, to intervene to challenge that order for the benefit of non-parties. Cf. *Dandong v. Pinnacle Performance Ltd.*, 2012 WL 6217646, at *2 (S.D.N.Y. Dec. 3, 2012) (“The consent of the parties is not a valid basis to justify sealing, as ‘the rights involved are the rights of the public.’”) (citation omitted). The fact that none of the Propecia plaintiffs has challenged the continued sealing of the Sealed Exhibits thus has no bearing on the public’s right of access here.

Second, Defendants argue that the First Amendment right of access cannot apply because the case was settled prior to a decision on Defendants’ motions. See Defs. Opp’n 15. But the Second Circuit already considered and rejected such reasoning in *Lugosch*. There, the district court held in abeyance a newspaper’s motion to intervene and unseal until after it ruled on a summary judgment motion. The court held that it was impossible to determine the strength of the presumption of access since the court could decide the summary judgment motion on procedural grounds without considering the record, the court could deny summary judgment after finding a question of fact on a single issue, or “the motions may be withdrawn or the case settled before the Court issues its decision, as a result of which there will have been no judicial action with respect to which the documents may be relevant or useful.” *Lugosch*, 435 F.3d at 116 (quoting *Lugosch v. Congel*, 2005 WL 1523409, at *3 (N.D.N.Y. June 24, 2005)). The Second Circuit rejected the district court’s explanation and found that the highest presumption of access applied. *Id.* at 123-24. It explained, “[o]nce those submissions come to the attention of the district judge, they can fairly be assumed to play a role in the court’s deliberations” and “to equate the weight of the presumption with the disposition of each particular claim would require the Court to review the documents under varying standards, which would be extremely difficult and a waste of judicial resources.” *Id.* at 123 (citation omitted); see also *Bernstein v. Bernstein Litowitz Berger & Grossmann LLP*, 814 F.3d 132, 140, 143 (2d Cir. 2016) (holding that complaint is judicial record

subject to First Amendment right of access even when case speedily settles because the public can still learn about “the nature of the parties” and “settlement rates,” among other things, and because the court may still have “engage[d] in adjudicatory duties”). Indeed, any other ruling would lead to the absurd result that a media organization that intervenes prior to settlement would be entitled to a First Amendment presumption of access, while the same entity, seeking the exact same documents, would be entitled to a lesser presumption after the case has settled.

Accordingly, because the Sealed Exhibits relate to Plaintiff’s summary judgment and *Daubert* briefing, they are entitled to a strong presumption of access.

3. Defendants’ Arguments Against Access Are Unavailing

Defendants last argue that even if the Sealed Exhibits are entitled to some presumption of access, there are “countervailing factors” that militate against unsealing. Defs. Opp’n 12-13. However, the presumption of access can only be overcome if a party seeking to seal demonstrates that there is a “substantial probability of harm to a compelling interest.” *See* Mot. 7. Here, it is particularly difficult for Defendants to make the requisite showing, since much of the information that remains under seal has already been disclosed through Plaintiff’s mis-redacted brief.³ Given this context, none of the reasons for sealing proffered by Defendants is “compelling.”

a. Any “Competitive Business Information” Contained in the Sealed Exhibits Is Likely Stale and Does Not Warrant Wholesale Sealing

Defendants argue that the Sealed Exhibits contain information that would “reveal internal

³ Plaintiff alleges that Reuters “hack[ed]” the court documents in order to gain access to the redacted material. *See* Pl. Opp’n ¶ 14. This rhetorical flourish is far from the truth. Any individual with an ECF account can download Plaintiff’s brief, and a search of the document using the “control+f” function on any computer makes clear that the text behind the redactions is accessible. Further, Reuters reached out to Defendants in July 2019 – over one month before filing its brief or publishing its articles – to alert Defendants that it “was able to read the material under the redacted portions [of documents filed in the *Dawson* matter] by highlighting the text and copying it into a Word document” and that the redacted material “contains details about Merck’s clinical trials.” Defs. Opp’n Ex. 1 (7/18/2019 email from D. Levine to C. Gillespie). Despite this knowledge, it appears that Defendants did not request that Plaintiff or the Court fix the redactions or that Reuters not publish its article due to the highly sensitive nature of the mis-redacted material.

business strategies and significantly harm a party's competitive interests." Defs. Opp'n 13.⁴ But the case at hand differs greatly from those that Defendants rely upon. In *Oliver Wyman, Inc. v. Eielson*, 282 F. Supp. 3d 684, 706 (S.D.N.Y. 2017), for example, the court held that documents showing "the average Oliver Wyman partner compensation," and the firm's "internal analysis of the competitiveness of its practice groups" could harm the firm's competitive standing. Yet based on the mis-redacted information from Plaintiff's Brief, the Sealed Exhibits, unlike those in *Oliver Wyman*, do not contain current information or internal analyses that could harm Defendants' competitive standing. Instead, the Sealed Exhibits include communications with regulators from the early 2000s, the results of Merck internal studies from the 1990s, and opinions from various individuals employed by Merck during that time. It is unclear how historic documents could cause competitive harm to Defendants over a decade later. Moreover, the cases that Defendants cite do not stand for the broad proposition that documents containing confidential business information should be fully sealed. Instead, when possible, the courts ordered the parties to produce the documents with narrow redactions for competitive information. See *Seoul Viosys Co. v. P3 Int'l Corp.*, 2018 WL 4759744, at *13-14 (S.D.N.Y. Sept. 30, 2018). Here too, if any of the Sealed Exhibits truly contain information that would hurt Defendants' current competitive standing, they can still be unsealed with redactions for that information. To the extent an *in camera* review is necessary for the Court to make such a determination, Reuters consents to the review.

b. Merck's Alleged "Transparency" Is Not an Adequate Substitute for the Presumption of Access

Defendants also seem to believe that, because they submitted data to the FDA and

⁴ Defendants also briefly state, "[t]rade secrets are another category of competitive business information which would warrant sealing." Defs. Opp'n 13. But Defendants never actually argue that the Sealed Exhibits contain trade secrets, and "an assertion of confidential business information, without more, will not merit trade secret protection." *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 WL 889799, at *6 (E.D.N.Y. Mar. 8, 2010).

published certain findings in peer-reviewed literature, they should be shielded from a traditional access analysis. Defs. Opp’n 4-5. Initially, the fact that Defendants made some of the information contained in the Sealed Exhibits available through articles cuts against their current requests for secrecy—once information has been made public, a party can no longer argue that it should be shielded from public access. *See, e.g., Alexsam, Inc. v. Mastercard Int’l Inc.*, 2017 WL 9750837, at *3 (E.D.N.Y. Mar. 13, 2017) (plaintiff cannot make the requisite showing to seal a document when “almost all of what it seeks to redact is already in the public record, and much of it was put there by [plaintiff] itself”). More importantly, Constitutional rights – including the public’s right of access under the First Amendment – do not yield merely because a company believes it has complied with regulatory obligations. To the contrary, even communications with regulators, like the FDA, are not shielded from public access. *See King Pharms., Inc. v. Eon Labs, Inc.*, 2010 WL 3924689, at *8 (E.D.N.Y. Sept. 28, 2010) (“Simply put, the communication of information to the FDA in connection with a drug application does not automatically trigger protection against disclosure.”). Moreover, when Reuters contacted the FDA, the FDA declined to discuss with the journalists details of the information that Merck provided to it. Thus, Defendants’ communications with the FDA clearly do not substitute for providing the public with access to the filed documents and do not relieve Defendants from showing the particularized harm that would result from unsealing the Sealed Exhibits—which they fail to do.

CONCLUSION

The public is not required to accept Merck’s claims of “transparency” at face value. For the foregoing reasons, Reuters respectfully requests that this Court grant its motion to intervene, remove the already public redactions from Plaintiff’s Opposition to Defendants’ Motion to Exclude Experts, and unseal the corresponding Sealed Exhibits.

Dated: New York, New York
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Respectfully submitted,

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